

## **REMARKS**

### ***Summary of Changes Made***

The undersigned would like to thank Examiner John Pak for his time on the telephone several times over a period of months, most recently 22 and 26 September 2008, to discuss various issues of the application.

The application was filed with 11 claims. In a preliminary amendment filed together with the application, claims 12-17 were added. In another amendment, claims 9-11 were canceled and claims 1-8 and 12-17 were amended, while claims 18-21 were added. An Amendment After Final filed 2 September 2008 (Amendment C) was not entered into the record. In the present amendment, which also serves as a Request for Continued Examination, claims 18 and 19 are amended to recite that they are composition claims, depending from claim 1; the dependency on a "process" that was erroneously included has been eliminated. New claims 22 - 30 are added herein.

It was stated in the previous amendment, filed 5 February 2008, that a terminal Disclaimer had been filed. This statement was in error, and no terminal disclaimer has been filed and none is included herewith. Applicants note for the record that certain claims of commonly owned copending Application Ser. No. 11/815,568 have been canceled to overcome a provisional double patenting rejection herein, which is more fully described hereinbelow. Applicants note that the Examiner has indicated this provisional rejection has been overcome in the Advisory Action of 2 September 2008, as only claim objections or claim allowances were indicated therein. Accordingly, claims 1-8 and 12-21 (18 claims) remain pending in the application. The only outstanding issue is the objection to claim 2, and hence the claims that depend therefrom. No new matter is added by this amendment.

### ***Allowed and Allowable Claims***

In the Advisory Action of 2 September 2008, the Examiner indicated that claims 1, 7, and 8 were allowed, and claims 18 and 19 would be allowable if they were corrected to properly depend from claim 1, that is, indicate that the subject matter of claims 18-19 were directed to the same water soluble iron carbohydrate complex of claim 1. The Examiner will note that claims 18 and 19 are so amended. Applicants believe that claims 18 and 19 are now in allowable form.

***Claim Objections - 37 C.F.R. §1.75(c)***

The Examiner objected to claims 2-6, 12-17, 20, and 21 for improper dependent form as failing to further limit the subject matter of a previous claim. The Examiner contends that claim 2, a method claim, recites a method of producing the complex of claim 1. However, the Examiner asserts that claim 2 lacks language that ensures the production of a complex having a molecular weight of 80,000 to 400,000, as recited in claim 1. The remaining claims under this rejection all ultimately depend from claim 2.

The Examiner will note that claim 2 has been amended to fully independent form to recite that the claimed process produces “a water soluble iron carbohydrate complex having a weight average molecular weight (Mw) of 80,000 to 400,000.”

In the Advisory Action of 30 September 2008, the Examiner declined to enter Amendment C, filed 2 September 2008, which contained an amendment to claim 2 to fully independent form as it

“raise[s] a different, new issue in that [ ] claim [2] would then appear to be missing an essential element, i.e., steps that actually produce the average molecular weight feature are missing. The oxidation of maltodextrin has no limit on how much it can proceed to cleave and modify the maltodextrin structure, so there must be adequate process steps/language that ensure that the ‘process for producing’ actually says what it does.”

In the Interview Summary mailed together with the Advisory Action, the Examiner stated that during the interview of 26 September 2008, the

“Examiner explained that the ‘process for producing’ does no such thing because the process does not have any steps that would assure the oxidized products of maltodextrin would stay within average molecular weight of 80,000 to 400,000. No temperature, time or pH conditions are specified, which would provide for the stated claim-required molecular weight feature.”

Paragraph 22 of the instant specification (as set forth in U.S. Pat. App. Pub. No. 2006/0205691, to which all specification references will be made) clearly discloses that the inventive method results in complexes having a weight average molecular weight of 80,000 to 400,000. Further, the Examiner will note that all examples of the inventive process result in complexes having molecular weights within this claimed range.

Claim 2 does, in fact, specify conditions that will result in the iron-carbohydrate complexes of the invention having a molecular weight of 80,000 to 400,000. The dextrose equivalent (DE) of the maltodextrin is a measure of the amount of terminal aldehyde groups of

the maltodextrin that are oxidized to carboxyl groups, as noted in paragraph [0009] of the patent application publication. The carboxyl groups serve as centers for reaction with the iron (III) salt to form the complex of the invention. Hence, if a lower DE maltodextrin is used, there are relatively fewer terminal carboxyl groups resulting from oxidation of aldehyde groups, thus resulting in a higher molecular weight complex. If a higher DE maltodextrin is used, there are relatively more terminal carboxyl groups resulting from oxidation of aldehyde groups, thus resulting in a lower molecular weight complex. Compare Examples 3, 4, and 5. Taking them in the order, Example 4, Example 3, Example 5, one sees that the starting DE of each example are 6.6, 9.6 and 14.0, respectively. Taken in the same order, one sees that the resulting complexes have molecular weights of 189, 140 and 118<sup>1</sup>, respectively, all within the claimed range. Hence, as the DE of the maltodextrin rises, the molecular weight falls. The dextrose equivalents in the range specified in claim 2 will result in molecular weights specified in claim 2.

Based on the foregoing, Applicants request withdrawal of the objection to claims 2-6, 12-17, 20 and 21.

***Claim Rejections – Non Statutory Obviousness-Type Double Patenting***

Claims 1-4, 7, 8, 12, 18, and 19 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 13-16, 26 and 27 of commonly owned copending Application No. 11/815,568 in view of Thaburet and Dokic. The Examiner contends that Claim 26 of the copending application sets forth a process of making an iron (III) maltodextrin complex comprising contacting maltodextrin having a DE of 5-37 with an aqueous hypochlorite solution having a pH of greater than 7 to form a reaction mixture and contacting the mixture with an aqueous iron (III) salt solution. Claims 13 and 16 of the copending application allegedly set forth a medicament comprising a complex of an oxidation product of at least one maltodextrin with iron (III) in various medication forms. The discussion of the secondary references is incorporated herein by reference. The Examiner concludes that the skilled artisan would have found it obvious to use the known processes for oxidizing carbohydrates, including dextrans, and that carbohydrates and oxidized dextrans are also known for delivering iron to subjects in need thereof.

The Examiner will note, and apparently has already noted, that a Preliminary Amendment

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<sup>1</sup> The molecular weight of the resultant complex of Example 5 is 118 kDa, and not 1118 kDa. This is a typographical error in the Patent Application Publication. Reference to Example 5 in the specification as filed at page 12 line 8 to page 13 line 1 confirms this molecular weight of 118 kDa.

has been filed in the cited copending application (U.S. 11/815,568), a copy of which, together with the filing receipt therefor, (6 pages total) is enclosed herewith, for inclusion in the record of the instant application. The EFS ID for the filing receipt of said Preliminary Amendment is 3870932. The Preliminary Amendment in the copending application cancels claims 13-16, 26, and 27 thereof. Thus it is believed the grounds for such rejection herein have been removed, rendering moot the provisional double patenting rejection.

Indeed, Applicants note that the Examiner has indicated this provisional rejection has been overcome, as no mention of such rejection was made in any Advisory Action issued subsequent to the Final Office Action of 1 May 2008.

***Translation of CN 2002061- (HCAPLUS Abstract 2003:135397)***

The Examiner has kindly provided a full English translation of CN 20020612, previously cited as HCAPLUS Abstract 2003:135397 ("HCAPLUS2"). Applicants expressly acknowledge that the Examiner has not further applied the reference as a result of the translation. It is hence believed that the argumentation in the Amendment filed 5 February 2008 has overcome the rejection of claims 1-8 and 11-17 are 35 U.S.C. 103(a) as unpatentable over HCAPLUS2 in view of Thaburet and Dokic.

***New Claims 22-30***

New claims 22-30 have been added to round out Applicants' claim coverage. Claim 22 recites a process for producing the water soluble iron carbohydrate complex of the invention and also specifies several reaction parameters, such as the pH of 8-12, the temperature of 15-40 °C, and the time of about 10 minutes to about 4 hours. It is also specified that the pH of the oxidized maltodextrin solution is raised to a value in the range of 5-14. Support for these limitations are found in the claims as they previously stood and in the specification in paragraphs [0008] and [0015]. Support for the limitations of claim 23 are found in paragraph [0008]. Claims 24 and 25 are supported in paragraph [0015]. Claim 26 is supported in paragraph [0018], while claims 27 and 28 find support in paragraph [0019]. Claims 29 and 30 both find support in Example 1, paragraph [0029]. It is believed that such the limitations of claim 22 are sufficiently precise such that claims 22-30 are not subject to the objection currently in place with respect to claim 2 and its dependent claims.

### **ERROR IN PATENT APPLICATION PUBLICATION**

Applicants state for the record that the publication of the instant application, U.S. Pat. App. Pub. No. 2006/0205691 (referred to above for specification references) contains typographical errors introduced at the publication stage, errors which do not appear in the official record.

Paragraph 42 thereof currently reads, in part, "in a range of 10.85" and should read "**in a range of 1:0.85,**" as seen in Example 3 of the specification as originally filed at page 10, line 34. Further, paragraph 56 contains the erroneous "1118 kDa," which should be "**118 kDa,**" as seen in Example 5 in the specification as filed at page 12 line 8 to page 13 line 1.

A careful reading of the specification as filed will reveal that the above errors were not in the original, but introduced in the patent application publication.

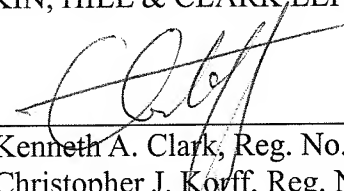
### **CONCLUSION**

Based on the foregoing, the Applicants respectfully request entry of the instant amendment and a Notice of Allowability for claims 1-8 and 12-30. If it is determined that the application is not in a condition for allowance, the Examiner is invited to initiate a telephone interview with the undersigned attorney to expedite prosecution of the present application. If there are any additional fees resulting from this communication, please charge the same to our Deposit Account No. 18-0160, our Order No. GIL-15940.

Respectfully submitted,

RANKIN, HILL & CLARK, LLP

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## Electronic Acknowledgement Receipt

|   |                                      |
|---|--------------------------------------|
| <b>EFS ID:</b>                              | 3870932                              |
| <b>Application Number:</b>                  | 11815568                             |
| <b>International Application Number:</b>    |                                      |
| <b>Confirmation Number:</b>                 | 9041                                 |
| <b>Title of Invention:</b>                  | Use Of Iron(III) Complex Compounds   |
| <b>First Named Inventor/Applicant Name:</b> | Jessica Tanner-Baumgartner           |
| <b>Customer Number:</b>                     | 07609                                |
| <b>Filer:</b>                               | Kenneth A. Clark/Kathryn Kallay      |
| <b>Filer Authorized By:</b>                 | Kenneth A. Clark                     |
| <b>Attorney Docket Number:</b>              | GIL-17476                            |
| <b>Receipt Date:</b>                        | 02-SEP-2008                          |
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| <b>Application Type:</b>                    | U.S. National Stage under 35 USC 371 |

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| Submitted with Payment | no                   |                    |  |                  |                  |
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| <b>File Listing:</b>   |                      |                    |  |                  |                  |
| Document Number        | Document Description | File Name          | File Size(Bytes)/<br>Message Digest                    | Multi Part /.zip | Pages (if appl.) |
| 1                      |                      | gil17476prelim.pdf | 289928<br>0a32ea9587775d0308012cf81ef27de3d13f<br>b9d3 | yes              | 4                |

|  | Multipart Description/PDF files in .zip description |       |     |
|--|---|-------|-----|
|  | Document Description                                | Start | End |
|  | Preliminary Amendment                               | 1     | 1   |
|  | Claims  | 2     | 3   |
|  | Applicant Arguments/Remarks Made in an Amendment    | 4     | 4   |

**Warnings:**

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**New Applications Under 35 U.S.C. 111**

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

**National Stage of an International Application under 35 U.S.C. 371**

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

**New International Application Filed with the USPTO as a Receiving Office**

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

|                   |   |                                    |
|-------------------|---|------------------------------------|
| Application. No.  | : | 11/815,568                         |
| Confirmation. No. | : | 9041                               |
| Applicant(s)      | : | Jessica Tanner-Baumgartner et al.  |
| Filed             | : | 3 January 2008                     |
| Title             | : | Use of Iron(III) Complex Compounds |
| TC/A.U.           | : | 1796                               |
| Examiner          | : | none                               |
| Docket No.        | : | GIL-17476                          |

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**PRELIMINARY AMENDMENT "B"**

Sir:

Prior to examining the application and calculating the filing fee, please amend the above-identified application as follows:

- **Amendments to the Claims** are reflected in the Listing of Claims, which begins on page 2 of this paper.
- **Remarks/Arguments** begin on page 4 of this paper.



## **AMENDMENTS TO THE CLAIMS**

The following listing of claims will replace all prior versions, and listings, of claims in the application:

### **Listing of Claims**

Claims 1-16 (canceled)

Claim 17 (currently amended): A method of improving brain function comprising administering to a patient a medication comprising an iron(III) compound selected from the group consisting of iron(III) polymaltose and an iron(III)maltodextrin complex, the iron(III) maltodextrin complex comprising a complex of an oxidation product of one or more maltodextrins with iron(III), wherein the ~~pateient~~ patient may be of any age.

Claim 18 (previously presented): The method of claim 17, wherein the iron(III) compound is an iron(III) polymaltose complex having a molecular weight ( $M_w$ ) of 20,000 to 500,000.

Claim 19 (previously presented): The method of claim 17, wherein the iron(III) compound is an iron(III) polymaltose complex having a molecular weight ( $M_w$ ) of 30,000 to 80,000.

Claim 20 (previously presented): The method of claim 17, wherein the iron(III) compound is an iron(III) maltodextrin complex having a molecular weight ( $M_w$ ) of 30,000 to 500,000.

Claim 21 (previously presented): The method of claim 17, wherein the medication is administered intravenously, intramuscularly, or orally.

Claim 22 (previously presented): The method of claim 17, wherein the patient is selected from the group consisting of (a) anemic patients having iron deficiency, (b) non-anemic patients having iron deficiency, (c) non-anemic patients not having iron deficiency, and (d) patients with no iron deficiency.

Claim 23 (previously presented): A method of improving at least one of neutrophil level, antibody level, and lymphocyte function as measured by lymphocyte reaction to phytohemoglobin, the method comprising administering to a patient a medication comprising an iron(III) compound selected from the group consisting of iron(III) polymaltose and an iron(III)maltodextrin complex, the iron(III) maltodextrin complex comprising a complex of an oxidation product of one or more maltodextrins with iron(III).

Claim 24 (previously presented): The method of claim 23, wherein the iron(III) compound is an iron(III) polymaltose complex having a molecular weight ( $M_w$ ) of 20,000 to 500,000.

Claim 25 (previously presented): The medication of claim 23, wherein the iron(III) compound is an iron(III) polymaltose complex having a molecular weight ( $M_w$ ) of 30,000 to 80,000.

Claims 26-27 (canceled)

Claim 28 (new): A method of improving immune defense comprising administering to a patient a medication comprising an iron(III) compound selected from the group consisting of iron(III) polymaltose and an iron(III)maltodextrin complex, the iron(III) maltodextrin complex comprising a complex of an oxidation product of one or more maltodextrins with iron(III), wherein the patient may be of any age.

**REMARKS**

*Summary of Changes Made*

The application was filed with claims 1-12. Claims 1-12 were canceled in a previous amendment. Claims 13-16, 26, and 27 are canceled herein to overcome a double-patenting rejection in commonly owned copending application number 10/531,895 (Docket No. GIL-15940). New claim 28 is added to round out Applicant's claim coverage, and claim 17 is amended to correct a typographical error. Support for claim 28 is found in the subject matter of canceled claim 13 and claim 17. Thus, claims 17-25 and 28 (10 claims) remain pending in the application. No new matter is added hereby.

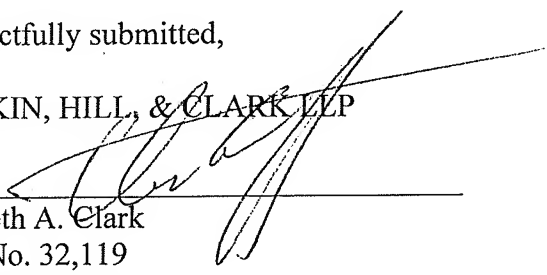
**CONCLUSION**

In light of the foregoing, it is respectfully submitted that the present application, is in condition for allowance and notice to that effect is hereby requested. If it is determined that the application is not in a condition for allowance, the Examiner is invited to initiate a telephone interview with the undersigned attorney to expedite prosecution of the present application.

If there are any additional fees resulting from this communication, please charge the same to our Deposit Account No. 18-0160, our Order No. GIL-17476.

Respectfully submitted,

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